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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,946	09/29/2003	Ashish Varma	PA1436	8308

28390 7590 11/15/2006
MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

JASTRZAB, KRISANNE MARIE

ART UNIT PAPER NUMBER

1744

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/671,946	VARMA ET AL.	
	Examiner	Art Unit	
	Krisanne Jastrzab	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/04,01/05</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

The use of the trademarks Clear Ez Peel®, Tyvek®, PEBAX®, VESTMID®, GRILON®, AGELESS, MODURAN, and SECUR has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to because of the following informalities: the specification includes recitations of trademarks without their accompanying generic terminology.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 15 are found to be vague and indefinite because of their inclusion of trademarks which are not properly described in the specification with their generic terminology.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 9-17, 18-21 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over George U.S. patent No. 5,014,494 in view of Lee et al., U.S. publication 2003/0083616 A1.

George teaches a method of sterilizing a sensitive polymeric medical device wherein the device is packaged in a gas impermeable package, nitrogen is used to purge any oxygen from the package, and the package is irradiated with either electron beam or gamma radiation to sterilize the device. The package material is preferably a multilayer material with polymeric layers and an aluminum layer, the aluminum layer providing the greatest oxygen barrier. See column 1, lines 20-25 and column 2 lines 10-55.

Lee et al., teaches that it is known and expected that dilation catheter balloons are sensitive polymeric medical devices that benefit from radiation sterilization. Radiation sterilization of the balloons is performed with the balloon packaged in a multilayer pouch formed from a polyester layer, aluminum foil layer and a polyethylene layer. The balloons themselves are recognized as being generally formed from polyether-block co-polyamides, nylons, and PET. Atmospheres within the pouch are inert by flush with a gas such as nitrogen to protect the device from deleterious oxidation. Radiation is applied at doses levels generally between 25 and 75 kGys. See page 8, paragraphs 0097, 0098 and 0107, page 10, paragraphs 0128 and 0134, page 11, paragraphs 0138-0140, page 16, Examples 16 and 17, and page 17, Examples 18-19

It would have been obvious to one of ordinary skill in the art to apply the method of George to the packaged balloon as taught in Lee et al, because it is recognized that such balloons benefit from radiation sterilization, and the control of the method of

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George would minimize any deleterious effects of that sterilization on the polymeric balloon.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlqvist et al., U.S. patent No. 5,881,534 in view of Lee et al., '616.

Ahlqvist et al., teach sterilization of sensitive polymeric medical devices by placing the device in a gas impermeable multilayer package preferably including an aluminum foil layer, purging oxygen from the package with an inert gas such as nitrogen and irradiating the packaged device with either electron beam or gamma radiation at claimed dose levels. The package includes an oxygen absorbent to ensure minimal levels of oxygen to prevent polymeric deterioration thereby. Ahlqvist et al., are silent as to the specific application of the method to balloons. See the abstract, column 5, lines 10-45, column 6, lines 5 –55 and column 7, lines 33-35.

Lee et al., is applied as set forth above.

It would have been obvious to one of ordinary skill in the art to apply the method of Ahlqvist et al., to the packaged balloon as taught in Lee et al, because it is recognized that such balloons benefit from radiation sterilization, and the control of the method of Ahlqvist et al., would minimize any deleterious effects of that sterilization on the polymeric balloon.

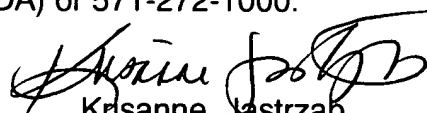
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Thurs. 6:00am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Krisanne Jastrab
Primary Examiner
Art Unit 1744

November 13, 2006